

REMARKS

Claims 1, 2, 4-6, 8-11, 13 and 14 are pending in the application. All of the pending claims stand rejected. Claims 15-17 have been withdrawn. Claims 3, 7 and 12 were previously canceled without prejudice.

I. Withdrawal of the Rejection under 35 USC § 102(b)

Applicants acknowledge with appreciation the Examiner's reconsideration and withdrawal of the previous anticipation rejection.

II. Rejection under 35 USC § 103(a)

Claims 1, 2, 4-6, 8-11, 13 and 14 have been rejected as allegedly obvious over Gentile *et al.* (US 2006/0140816 and EP 1454636), in view of Karlsson *et al.* and McAffer *et al.*

The primary cited reference, Gentile *et al.* (US 2006/0140816), was published June 29, 2006, with a 371(c) date of 08-08-2005, and a priority claim to International application PCT/EP04/50235, which has an International Filing Date of March 2, 2004. Gentile *et al.* (EP 1454636) was published September 8, 2004, based on an EP filing date of March 4, 2003, wherein international application PCT/EP04/50235, with an International Filing Date of March 2, 2004, is in the continuity chain of EP 1454636.

Applicants respectfully submit that the claimed invention was reduced to practice prior to the effective date of either US 2006/0140816 or EP 1454636.

Applicants submit herewith a Declaration under 37 CFR §1.131, by all of the inventors of the instant invention in order to establish their invention date prior to March 2, 2004, and thereby eliminate Gentile *et al.*, US 2006/0140816 and EP 1454636 as prior art references against the instant application. The Declaration provides supporting evidence, in the form of the original lab notebook record of the experiments disclosed in Example 1 of the application, showing that the subject matter of the claimed invention was reduced to practice prior to March 2, 2004.

Applicants' representative notes that, in their executed Declarations, Donald MacDonald, John Miller and Adrian Ashley corrected the error in listing a doctorate degree as their highest academic degree. The error in listing the wrong academic degree for three of the inventors was a clerical error and was unintentional, and was corrected by the inventors themselves as they executed their copies of the Declaration.

Applicants' representative also notes that John Miller inadvertently signed the Declaration on the line below his name instead of the line corresponding to his name. This error was also unintentional.

Since Applicants have established that the reduction to practice of the claimed invention occurred prior to March 2, 2004, the Gentile *et al.* references do not qualify as prior art under either 102(e) or 102(a).

Applicants discussed the secondary references, Karlsson *et al.* and McAffer *et al.* in detail in the response dated December 31, 2009. As explained in that response, Karlsson's teaching relates to dry sterilization of powdered forms of glucocorticosteroid. Karlsson only taught formulation of the aqueous suspension of the glucocorticosteroid after carrying out the dry sterilization. McAffer *et al.* taught several different sterilization processes, but did not teach or suggest the claimed process. Moreover, considering the challenges and unpredictability that were recognized by both Karlsson and McAffer, the teaching provided by those references would not have provided the skilled person with the requisite *reasonable expectation of success* in modifying those disclosed processes to achieve Applicants' claimed process.

In light of the disqualification of the primary references (Gentile *et al.*), and the failure to establish *prima facie* obviousness solely over the two secondary references, Applicants respectfully ask that the Examiner reconsider and withdraw the obviousness rejection.

III. Non-statutory Double Patenting Rejection

Claims 1-4, 6, 7 and 9-13 have been provisionally rejected for obviousness-type double patenting over claims 1, 3, 6, 9, 10, 13 and 15 of copending US Application 11/667,872.

Applicants still maintain that the claims of copending US Application 11/667,872 provide no teaching or suggestion of any need or advantage of the claim element requiring that at least 70% of the glucocorticosteroid exist in the form of a suspension during the sterilizing process.

Nonetheless, solely to expedite allowance of the instant application, Applicants submit herewith a Terminal Disclaimer under 37 CFR 1.321 over copending US Application 11/667,872. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the nonstatutory double patenting rejection.

In light of the discussion above and the herewith filed Terminal Disclaimer, Applicants believe that all claims in this Application are in condition for allowance.

The time for responding to the Office Action was set for June 11, 2010. This Response is being timely filed in view of the accompanying Petition under 37 CFR § 1.136 for a two-month extension, which extends the time for response through August 11, 2010. Please charge the extension fee, and any other fees, which may be required for the filing of this response, to Deposit Account No. 18-0350.

Respectfully submitted,



Christopher R. Lewis/ Reg. No. 36,201
Stephen D. Harper, Reg. No. 33,243
Attorneys for Applicants

CRL/SDH/ams

Dated: August 9, 2010

P.O. Box 980
Valley Forge, PA 19482
(610) 407-0700

The Director is hereby authorized
to charge or credit Deposit
Account No. 18-0350 for
any additional fees, or any
underpayment or credit for
overpayment in connection
herewith.

1010251